

REMARKS

Applicant hereby affirms the election to prosecute the invention of Group I, i.e., claims 1-17. Claims 18-24 are now canceled, without prejudice, as being drawn to non-elected inventions.

Applicant has amended claims 5 and 8 to more particularly claim the subject matter which applicant regards as his invention. Support can be found, for example, at page 27, line 20 to page 28, line 26 and page 2, lines 10-11 of the specification. Applicant has also amended the specification to correct a typographical error.

Claims 1-17 are now pending. Consideration of the application, as amended, is respectfully requested in view of the remarks below.

Drawings

The drawings in the present application are objected to, as stated in the Office Action, page 4, item 2. Applicant will correct the drawings upon allowance of the claims.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-17 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicant will address each of the Examiner's concerns below.

First, it is the Examiner's view that the term "reduced" recited in claim 1 is relative, and that the specification does not provide a standard. Applicant disagrees and directs the Examiner's attention to the sentence at page 23, lines 24-25 of the specification, which reads: "[r]educed valency CBLs refer[] to ligands which have been genetically engineered to have less than the normal valency." Thus, the term "reduced" means "less than normal;" or "less than the valency in the wild type CBLs." Applicant therefore submits that the term "reduced" recited in claim 1 is not indefinite.

Second, the Examiner asserts that the term "important" recited in claim 4¹ is a subjective term that lacks a comparative basis. Applicant has replaced the term "important" with "capable of participating," requiring that the residues be capable of being involved in the dimer-dimer interactions. The amendment overcomes the rejection.

Third, the Examiner asserts that claim 6 is indefinite because specific mutagenesis of Concanavalin A is recited in the absence of the base sequence of this protein. Specific identification of the base sequence, however, is not necessary because the identification of the amino acid sequences provides sufficient information. Moreover, the base sequences could, if desired, be readily obtained from the amino acid sequence information. Accordingly, claim 6 is not indefinite.

Finally, it is the Examiner's position that the phrase "a portion thereof" recited in claim 8 renders the scope of the claim unascertainable. Applicant has amended this phrase to a specific portion of an antibody, namely an antigen binding portion of an antibody. This amendment overcomes the indefiniteness rejection.

Double Patenting

Claims 1-17 have been rejected under the judicially created doctrine of double patenting in view of claims 1-17 of commonly assigned application bearing U.S. Serial No. 09/090,601. Upon allowance of the pending claims in the present application, a terminal disclaimer will be filed.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 3-4, and 7-17 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,342,789 ("Chick"). Each claim requires the presence of a **recombinant reduced valency** carbohydrate binding ligand (CBL). Thus, each claim requires that the CBL (1) be prepared by recombinant process and (2) have a reduced valency. As discussed above, "reduced valency" refers to valency that is less than that in the wild type.

¹ Applicant believes that the Examiner actually refers to claim 5 since claim 5, rather than claim 4, contains the term at issue.

Chick does not describe using reduced valency CBLs, let alone recombinant reduced valency CBL's. Rather, Chick merely suggests using CBL's generally. The absence of further disclosure regarding the CBLs means that Chick is using the wild type ligand which does not have a reduced valency and which is not prepared by a recombinant process. Chick, therefore, fails to describe each and every element of the claims, thereby precluding a rejection for lack of novelty.

Rejection under 35 U.S.C. § 103(a)

Claims 2, 5, and 6 stand rejected under 35 U.S.C. § 103(a) over Chick in view of the abstract of Cho et al., *Trends in Glycoscience and Glycotechnology*, January 1997 ("Cho").

Each of the rejected claims depends on claim 1. Claim 1 is drawn to a method of evaluating a carbohydrate (e.g., glucose) in a sample. The method involves contacting a recombinant reduced valency CBL (e.g., lectin) with the carbohydrate and a glycoconjugate containing the same carbohydrate in the sample. As discussed above, Chick, the primary reference, does not disclose a reduced valency CBL, let alone a recombinant reduced valency CBL. Rather, Chick describes using CBLs having normal valencies, e.g., wild type Concanavalin A.

There is no recognition in Chick that the accuracy achieved using CBLs with normal valencies is deficient or in need of improvement. To the contrary, the thrust of the Chick patent is that the performance of CBLs with normal valencies is acceptable. It was Applicant who later recognized the need for improving the sensitivity, and thus the accuracy, of the process described in Chick, particularly at low carbohydrate concentrations, and then achieved that improvement by using a recombinant reduced valency CBL.

Cho, the secondary reference, does not supply the motivation or the means to modify the Chick patent. Cho is no more than an academic study of the dimerization mechanism of galectin-1, and the functional differences between monomeric and dimeric forms of this protein. To study this mechanism, Cho employs two galectin-1 proteins mutated at a region responsible for subunit interactions. Cho, therefore, at most discloses that certain recombinant reduced valency CBLs can be produced. Cho does not, however, suggest any practical use for these materials other than as aids in a scientific study of the dimerization mechanism. Accordingly, it

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would not have been obvious to combine Chick with Cho to arrive at the claimed invention.

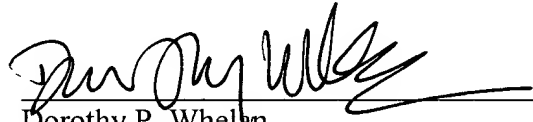
Applicant therefore requests that the rejection be withdrawn.

In view of the above, it is respectfully submitted that all of the claims now in the application are in condition for allowance, and such action is requested. If there are any additional charges, or any credits, please apply them to Deposit Account No. 06-1050.

Respectfully submitted,

Date: _____

4/5/01



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Version with markings to show changes made

In the specification:

Paragraph beginning at page 1, lines 11-16 has been amended as follows:

The invention is based on the discovery of reduced valency carbohydrate binding ligands (CBLs) that can be used to [to] detect or quantitate (i.e., evaluate) carbohydrates in a sample. CBLs can be used with fluorescence resonance energy transfer (FRET) to evaluate free carbohydrates or those within a carbohydrate containing compound.

In the claims:

Claims 18-24 have been cancelled, without prejudice, as being drawn to non-elected invention.

Claims 5 and 8 have been amended as follows:

5. (Amended) The method of claim 4, wherein the Concanavalin A is mutagenized at residues [important] capable of participating in dimer-dimer interactions to produce dimers which do not assemble into tetramers.

8. (Amended) The method of claim 7, wherein the label is a radioactive label, a fluorescent label, an enzyme, a proximity-based signal generating label moiety, a homogeneous time resolved fluorescence (HTRF) component, a luminescent oxygen channeling assay (LOCI) component, biotin, avidin, or an antibody or [a portion thereof] an antigen binding portion of an antibody.